

REMARKS

Claims 1-14 remain in the application for prosecution. Claims 15-20 are herein cancelled as being directed to non-elected subject matter. Applicant reserves the right to file Divisional applications on the subject matter of the non-elected claims. In addition, Applicant has made a species election, choosing apomorphine as a species of post synaptic dopamine receptor agonist compound, and fusaric acid as a species of noradrenalin inhibitor. Presently, claims 1-14 stand rejected.

Rejections under 35 USC §103

Claims 1-14 were rejected as being unpatentable over U.S. Patent No. 6,686,337 to Connor et al., in view of U.S. Patent No. 5,741,503 to Cincotta et al. Applicant respectfully traverses the rejection.

Connor et al. disclose combination therapies comprising anti-diabetic agents and anticonvulsant derivatives useful for the treatment of Type II diabetes mellitus and Syndrome X. Among the plethora of recited compounds, apomorphine is disclosed as "an appetite-suppressant agent acting through dopamine mechanisms".

Cincotta et al. disclose methods for regulating or ameliorating lipid metabolism which comprises administration of inhibitors of dopamine bet hydroxylase (DBH) such as fusaric acid. More specifically, the methods involve administration of fusaric acid in an amount effective to treat indices associated with lipid metabolism disorders (e.g., obesity, high cholesterol, and elevated levels of other blood lipids and lipoproteins) or indices associated with glucose metabolism disorders (e.g., glucose intolerance, insulin resistance, hyperglycemia, hyperinsulinemia, etc.) and/or with lipid metabolism disorders.

In contrast, claim 1 of the present invention recites a method for treating the metabolic syndrome or Type 2 diabetes in a patient, comprising the step of increasing the ratio of dopaminergic neuronal to noradrenergic neuronal activity within the hypothalamus of the central nervous system of said patient.

Claim 2 of the present invention recites a method for treating the metabolic syndrome or Type 2 diabetes, comprising the step of: administering to a subject in need of such treatment a pharmaceutical composition comprising (1) at least one compound that stimulates an increase in central dopaminergic neuronal activity level in said subject, such as apomorphine; and (2) at least one compound that stimulates a decrease in

central noradrenergic neuronal activity level in said subject, such as fusaric acid.

Applicant submits that the new and novel point of the invention is the discovery that patients suffering from metabolic syndrome or Type 2 diabetes may be treated by increasing the central dopaminergic neuronal activity level while simultaneously decreasing the central noradrenergic neuronal activity level as disclosed and particularly claimed in claim 2. Moreover, this simultaneous treatment results in an increase in the ratio of dopaminergic neuronal to noradrenergic neuronal activity within the hypothalamus of the central nervous system of the patient as disclosed and particularly claimed in claim 1.

Applicant submits that the presently claimed invention is not obvious in view of the cited references. While each of the cited references individually disclose possible compounds that stimulate an increase in central dopaminergic neuronal activity level or a decrease in central noradrenergic neuronal activity level, there is no teaching, suggestion, or recognition in any of the references that metabolic syndrome or Type 2 diabetes can be treated by simultaneously increasing the central dopaminergic neuronal activity level and decreasing the central noradrenergic neuronal activity level such that the ratio of dopaminergic

neuronal to noradrenergic neuronal activity within the hypothalamus of the central nervous system is increased. Moreover, there is no teaching, suggestion, or motivation in any of the art of record to combine any of the disclosed compounds, or what utility or effect such a combination might have. In sum, there is nothing in any of the references that would suggest to one of skill in the art that metabolic syndrome or Type 2 diabetes can be treated by simultaneously increasing the central dopaminergic neuronal activity level and decreasing the central noradrenergic neuronal activity level with any agent or combination of agents, much less a combination of apomorphine and fusaric acid.

For these reasons, Applicant submits the presently claimed invention is not obvious over the cited references, and that this rejection is overcome.

If the Examiner has any questions concerning this application, she is encouraged to contact the undersigned attorney.

Please charge any fees due with this response to Deposit
Account 23-1665 under Customer Number 27267.

Respectfully submitted,

ANTHONY H. CINCOTTA

By Todd E. Garabedian
Todd E. Garabedian, Ph.D.
Registration No. 39,197
Attorney for Applicant

WIGGIN and DANA LLP
One Century Tower
New Haven, CT 06508
Telephone: (203) 498-4400
Fax: (203) 782-2889

Date: 30 Nov 2007

\\15546\\5\\681308.1